UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., and PURDUE PHARMACEUTICALS L.P., Plaintiffs, v. KV PHARMACEUTICAL COMPANY, Defendant.	C.A. No. 07 Civ. 4810 (SHS) THIS DOCUMENT WAS FILED ELECTRONICALLY VIA CM/ECF
KV PHARMACEUTICAL COMPANY, Counterclaim Plaintiff, v. PURDUE PHARMA L.P., THE PURDUE FREDERICK COMPANY, THE P.F. LABORATORIES, INC., THE PURDUE PHARMA COMPANY, PURDUE PHARMACEUTICALS L.P., AND EUROCELTIQUE S.A., Counterclaim Defendants.	

PURDUE'S REPLY TO THE COUNTERCLAIMS SET FORTH IN DEFENDANT KV PHARMACEUTICAL COMPANY'S ANSWER AND COUNTERCLAIMS

Plaintiffs/counterclaim defendants Purdue Pharma L.P., The P.F. Laboratories Inc., and Purdue Pharmaceuticals L.P. and counterclaim defendants The Purdue Pharma Company, The Purdue Frederick Company, and Euroceltique S.A. (collectively, "Purdue") reply to Defendant/counterclaim plaintiff KV Pharmaceutical Company's ("KV") Counterclaims as follows:

REPLY

1. Denied.

2. KV purports to state causes of action based on alleged misconduct during the prosecution of Purdue patents before the United States Patent and Trademark Office ("PTO") and based on allegations that Purdue has wrongly brought suit to enforce its patents. Except as expressly admitted, Purdue denies the averments of Paragraph 2.

3. Denied.

4. Denied.

5. Purdue has brought suit to enforce its patents on several occasions. Except as expressly admitted, Purdue denies the averments of Paragraph 5.

6. Each of the entities listed in Paragraph 6 has either received approval of a New Drug Application ("NDA"), or filed an application for an Abbreviated New Drug Application ("ANDA"), with the U.S. Food & Drug Administration ("FDA") to manufacture and sell a competing controlled-release oxycodone product. Purdue has brought suit against each of the parties named in Paragraph 6. Except as expressly admitted, Purdue denies the averments of Paragraph 6.

7. Denied.

8. Admitted.

9. On February 1, 2006, the Federal Circuit vacated the judgment of this Court that Purdue's patents were unenforceable for inequitable conduct. *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1135 (Fed. Cir. 2006). The Federal Circuit found that Purdue had failed to disclose information of "relatively low" materiality, *id.* at 1134, but did not find that Purdue made material misstatements to the PTO, *id.* at 1133, or that Purdue had intent to deceive the PTO, *id.* at 1135. The Federal Circuit remanded to this Court for reconsideration of its intent

finding and, if necessary, reweighing of materiality and intent, noting that "[i]n making this determination, the trial court should keep in mind that when the level of materiality is relatively low, the showing of intent must be proportionately higher." *Id.* Except as expressly admitted, Purdue denies the averments of Paragraph 9.

10. Purdue has settled one or more lawsuits, including those against Endo Pharmaceuticals Inc. ("Endo"), Teva Pharmaceuticals USA, Inc. ("Teva"), and Impax Laboratories, Inc. ("Impax"). Other Purdue lawsuits continue. Except as expressly admitted, Purdue denies the averments of Paragraph 10.

11. Purdue brought suit against KV, Actavis Totowa LLC ("Actavis"), and Mallinckrodt Inc. ("Mallinckrodt") to enforce its patents. Except as expressly admitted, Purdue denies the averments of Paragraph 11.

12. Denied.

13. Denied.

14. Denied.

15. Denied.

16. Denied.

17. Denied.

18. KV purports to seek an order invalidating and/or rendering unenforceable Purdue's patents and for the specified relief. Except as expressly admitted, Purdue denies the averments of Paragraph 18.

19. On information and belief, Purdue admits that KV is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 2503 South Hanley Road, St. Louis, Missouri 63144. Except as expressly admitted, Purdue lacks

information sufficient to form a belief about the remaining averments of Paragraph 19, and therefore denies them.

20. Admitted.

21. Counterclaim Defendant The Purdue Frederick Company is a corporation organized and existing under the laws of the State of New York, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. The Purdue Frederick Company was at one time an assignee of the '912, '295, and '042 patents asserted in this action. Those patents and the '331 patent have since been reassigned to the plaintiffs. Except as expressly admitted, Purdue denies the averments of Paragraph 21.

22. Admitted.

23. Counterclaim Defendant The Purdue Pharma Company was a general partnership organized and existing under the laws of the State of Delaware. Purdue Pharma L.P. is the successor in interest to The Purdue Pharma Company. The Purdue Pharma Company was at one time an assignee of the '912, '295, and '042 patents asserted in this action. Those patents and the '331 patent have since been reassigned to the plaintiffs. Except as expressly admitted, Purdue denies the averments of Paragraph 23.

24. Admitted.

25. Euroceltique S.A. ("Euroceltique") is a Luxembourg corporation with its principal place of business at 122 Boulevard de la Petrusse, Luxembourg. Euroceltique is associated with the plaintiff companies. Euroceltique was the assignee of the '331, '912, '295, and '042 patents. Those patents have since been reassigned to the plaintiffs. Euroceltique is the assignee of the '598 and '075 patents. Except as expressly admitted, Purdue denies the averments of Paragraph 25.

26. Admitted.

27. KV purports to base subject matter jurisdiction on the statutes listed in Paragraph 27. Purdue does not contest that subject matter jurisdiction exists. Purdue's previous actions for patent infringement filed in the District of Delaware have been transferred to this Court for pretrial purposes as Civil Action Nos. 1:07 Civ. 03972 (SHS) and 1:07 Civ. 03973 (SHS) and consolidated with the existing Multidistrict Litigation 1:04-md-1603 pursuant to 28 U.S.C. § 1407. Except as expressly admitted, Purdue denies the averments of Paragraph 27.

28. Venue in this Judicial District is proper. Except as expressly admitted, Purdue denies the averments of Paragraph 28.

29. Denied.

30. Purdue has sold controlled-release oxycodone products in interstate commerce and in this Judicial District. Except as expressly admitted, Purdue denies the averments of Paragraph 30.

31. Purdue admits the averments in the body of Paragraph 31. With respect to footnote 2 of Paragraph 31, Purdue discontinued sales of the 160 mg dosage strength of OxyContin® in 2001. Except as expressly admitted, Purdue denies the averments of footnote 2 of Paragraph 31.

32. Controlled-release oxycodone is a single entity analgesic. Except as expressly admitted, Purdue lacks information sufficient to form a belief about the averments of Paragraph 32, and therefore denies them.

33. Purdue lacks information sufficient to form a belief about the averments of Paragraph 33, and therefore denies them.

34. One factor that may affect whether a doctor will prescribe a controlled-release formulation, as opposed to an immediate-release formulation of the same active ingredient, is that, in some cases, a controlled-release formulation may be taken fewer times per day. For patients for whom OxyContin® is indicated, OxyContin® can provide relief for 12 hours when taken as directed. There are immediate-release analgesics that are effective for only four to six hours. Except as expressly admitted, Purdue denies the averments of Paragraph 34.

35. On information and belief, the only companies other than Purdue to receive tentative or final approval from the FDA to market controlled-release oxycodone products are Roxane Laboratories, Inc., Endo, Teva, and Impax. Purdue has settled one or more lawsuits, including those against Endo, Teva, and Impax. Endo withdrew its product as of December 2006. Except as expressly admitted, Purdue denies the averments of Paragraph 35.

36. Denied.

37. Denied.

38. Denied.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

43. On information and belief, KV submitted Abbreviated New Drug Application ("ANDA") 78-506, pursuant to 21 U.S.C. § 355(j), for FDA approval to market a 15 mg strength controlled-release oxycodone product as a generic version of OxyContin® ("KV's Tablets"). Except as expressly admitted, Purdue denies the averments of Paragraph 43.

44. On information and belief, KV's ANDA included a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that Purdue's patents are invalid, unenforceable, or not infringed by KV's Tablets. Except as expressly admitted, Purdue denies the averments of Paragraph 44.

45. In a letter dated May 2, 2007 addressed to the plaintiffs, KV sent "notice" with respect to its 15 mg Tablets and the '912, '042, and '295 patents under 21 U.S.C. § 355(j)(2)(B)(ii). The plaintiffs received KV's letter on May 3, 2007. Except as expressly admitted, Purdue denies the averments of Paragraph 45.

46. Admitted on information and belief.

47. Plaintiffs filed suit against KV on June 6, 2007, within 45 days of receiving KV's Paragraph IV notice. Paragraph 47 otherwise states a conclusion of law to which no responsive pleading is necessary. Except as expressly admitted, Purdue denies the averments of Paragraph 47.

48. Paragraph 48 states a conclusion of law to which no responsive pleading is necessary. Except as expressly admitted, Purdue lacks information sufficient to form a belief about the averments of Paragraph 48, and therefore denies them.

49. Under the Food, Drug, and Cosmetic Act ("FDCA"), Purdue submitted for listing by the FDA in the FDA's "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) six patents, including the '331, '912, '042 and '295 patents. Paragraph 49 correctly identifies the title, filing date, issue date and named inventors of the specified patents. Paragraph 49 also correctly states the filing history of each of the patents except the '295 patent. The '295 patent is a continuation of the '912 patent, not a continuation in part. (*See*

‘295 patent, col. 1, lines 4-7). Except as expressly admitted, Purdue denies the averments of Paragraph 49.

50. Denied.

51. The named inventors of the ‘598, ‘075, ‘331, ‘912, ‘042, and ‘295 patents assigned their rights in those patents to Euroceltique. At the time they made those assignments, the four inventors were employed by one or more of the Counterclaim Defendants. Except as expressly admitted, Purdue denies the averments of Paragraph 51.

52. On May 14, 1999, Euroceltique assigned its rights in the ‘912, ‘042, and ‘295 patents to Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., and The Purdue Pharma Company. On May 18, 1999, these four entities asserted these patents in litigation against a group of patent infringers including Boehringer Ingelheim GmbH, Roxane Laboratories, Inc., and Boehringer Ingelheim Pharmaceuticals Inc. On October 10, 2006, Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., and The Purdue Pharma Company assigned their rights in the ‘912, ‘042, and ‘295 patents to the Plaintiffs. On June 6, 2007, Plaintiffs brought the present action against KV. Except as expressly admitted, Purdue denies the averments of Paragraph 52.

53. Denied.

54. Benjamin Oshlack, John J. Minogue, and Mark Chasin are named as inventors on the ‘331 patent. Benjamin Oshlack, John J. Minogue, Mark Chasin, and Robert F. Kaiko are named as inventors on the ‘912, ‘042, and ‘295 patents. Except as expressly admitted, Purdue denies the averments of Paragraph 54.

55. The ‘598, ‘075, ‘331, ‘912, ‘042, and ‘295 patents were all filed and issued between July 1986 and August 1997. Each patent states on its face that it was assigned to Euroceltique S.A. Except as expressly admitted, Purdue denies the averments of Paragraph 55.

56. An Examiner at the PTO evaluated the claims of each application for patentability under applicable rules. An applicant’s duty to disclose information material to patentability to the Examiner is defined by the version of 37 C.F.R. § 1.56, as amended, at the time a particular statement is made to the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 56.

57. Admitted.

58. Purdue overcame rejections raised by the Examiner as to each of the ‘331, ‘912, ‘042, and ‘295 patents. Except as expressly admitted, Purdue denies the averments of Paragraph 58.

59. Paragraph 59 inaccurately quotes the language appearing in the prosecution history of each of the ‘331, ‘912, ‘042, and ‘295 patents. The correct phrase is “[i]t has now been surprisingly discovered.” Purdue denies KV’s characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 59.

60. Paragraph 60 accurately quotes language appearing once in the prosecution history of the ‘331 patent except that the “o” in “Results Obtained” should be capitalized. (*See* ‘331 file history, Response filed October 22, 1992, Paper #4). Purdue denies KV’s characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 60.

61. Denied.

62. During the prosecution of the ‘912 patent, the Examiner rejected certain claims for obviousness. The applicants responded to the rejection. Ultimately, the ‘912 patent issued. Except as expressly admitted, Purdue denies the averments of Paragraph 62.

63. Denied.

64. The final study report cited in Paragraph 64 was completed before the ‘295 patent issued. Purdue did not disclose the study report to the PTO, nor was there any reason that Purdue should have disclosed it. The report was less pertinent than and cumulative to other facts that were before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 64.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

69. Paragraph 69 accurately quotes the cited portion of the Background of the Invention for the ‘598 and ‘075 patents except that it corrects “drub” to “drug” in line 2 and omits the comma between “consideration” and “when” in the last line. Purdue denies KV’s characterization of the quoted language. The table of dissolution rates set forth in Paragraph 69 incompletely quotes from the cited table in Example IIB of the ‘598 patent, omitting the time points and rates listed in the table for 3, 5, 8, and 9 hours. The other portions of the table reproduced in Paragraph 69 are accurate. Except as expressly admitted, Purdue denies the averments of Paragraph 69.

70. The claims of the ‘598 and ‘075 patents are directed to controlled-release formulations. The ‘598 patent contains a single dependent claim directed to compositions

"wherein said pharmaceutical agent is oxycodone." The specifications of the '598 and '075 patents do not refer to clinical studies. Mr. Oshlack's declarations filed during the pendency of the '598 and '075 patent applications do not refer to clinical studies. Except as expressly admitted, Purdue denies the averments of Paragraph 70.

71. Paragraph 71 accurately quotes the cited portions of the prosecution history of the '598 patent except that "CR" in the second quotation should be "controlled release." Except as expressly admitted, Purdue denies the averments of Paragraph 71.

72. Application Serial No. 07/800,549, which issued as the '331 patent, named Mr. Oshlack, Dr. Chasin, and Mr. Minogue as inventors and was filed and prosecuted by the law firm of Steinberg and Raskin. Except as expressly admitted, Purdue denies the averments of Paragraph 72.

73. Paragraph 73 accurately quotes the cited portion of the specification of the '331 patent except that it replaces "U.S Patent" [sic] with "US Pat." in the last sentence. The table of dissolution rates set forth in Paragraph 73 accurately states the time points and dissolution ranges from the cited portion of the specification of the '331 patent. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 73.

74. Paragraph 74 accurately quotes the cited portion of the specification of the '331 patent. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 74.

75. Admitted.

76. The Goldie '341 patent issued on February 5, 1991. It is prior art to the '331 patent under one or more subsections of 35 U.S.C. § 102 and is prior art to the '912, '042, and

‘295 patents under one or more subsections of 35 U.S.C. § 102. The Goldie ‘341 patent discloses, *inter alia*, a controlled-release oral dosage form containing hydromorphone and recites that “a peak plasma level at between 2-4 hours after administration gives at least 12 hours pain relief.” (‘341 patent, 2:20-22). The ‘331 patent recites the same for controlled-release formulations of oxycodone. (‘331 patent, 2:21-23). Portions of the Goldie ‘341 specification are identical to those of the ‘331 specification except that “hydromorphone” is changed to “oxycodone” in the ‘331 specification. Except as expressly admitted, Purdue denies the averments of Paragraph 76.

77. The Oshlack ‘598 patent issued on August 29, 1989. It is prior art under 35 U.S.C. § 102(b) to the ‘331, ‘912, ‘042, and ‘295 patents. The Oshlack ‘598 patent discloses, *inter alia*, two oxycodone base dosage forms in Example II and *in vitro* dissolution data for those oxycodone base formulations. Except as expressly admitted, Purdue denies the averments of Paragraph 77.

78. Paragraph 78 accurately quotes the cited portions of the prosecution history of the ‘331 patent. Purdue denies KV’s characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 78.

79. Paragraph 79 accurately quotes the cited portion of the prosecution history of the ‘331 patent except that there should be no hyphen in “controlled-release morphine” in line 2 and “similarly” should be “similar” in line 6. Purdue denies KV’s characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 79.

80. Paragraph 80 accurately quotes the cited portion of the prosecution history of the ‘331 patent. Purdue denies KV’s characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 80.

81. Admitted.

82. Admitted.

83. Paragraph 83 accurately quotes the cited portions of the February 25, 1993 Interview Summary Record. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 83.

84. Paragraph 84 accurately quotes the cited portions of the March 10, 1993 Amendment. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 84.

85. In support of the arguments made by Purdue's counsel before the PTO in the prosecution of the '331 patent application, Purdue submitted the declaration of Dr. Robert F. Kaiko. Dr. Kaiko identified himself as Vice President for Clinical Research for The Purdue Frederick Company, Norwalk, Connecticut. The Purdue Frederick Company is not mentioned elsewhere in the '331 file history. The '331 patent application identified Euroceltique as the assignee and did not name Dr. Kaiko as an inventor. No one presented Dr. Kaiko to the PTO as "disinterested, objective and independent" as KV alleges. Paragraph 85 accurately quotes the cited portions of the prosecution history of the '331 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 85.

86. Paragraph 86 accurately quotes the cited portions of the prosecution history of the '331 patent. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 86.

87. Denied.

88. The Oshlack '598 patent discloses, *inter alia*, two oxycodone base dosage forms in Example II and *in vitro* dissolution data for those oxycodone base formulations. Except as expressly admitted, Purdue denies the averments of Paragraph 88.

89. Paragraph 89 accurately quotes the cited portions of the specification of the Oshlack '598 patent except that italics have been added. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 89.

90. Denied.

91. Mr. Oshlack was named as an inventor on both the '331 and '598 patents. At least one of the same patent attorneys was involved in the prosecution of both of those patents, and both were at one time assigned to Euroceltique. Except as expressly admitted, Purdue denies the averments of Paragraph 91.

92. Paragraph 92 accurately quotes the cited portion of the prosecution history of the '331 patent. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 92.

93. Admitted.

94. Admitted.

95. Denied.

96. During prosecution of the '912 patent application, at the Examiner's suggestion, Purdue amended the specification "to obtain the benefit of the filing date of the prior application." ('912 file history, Paper #10, Sept. 12, 1995, p. 1). Purdue did not assert that any of the pending claims was entitled to the priority date of the '331 application. At no time did the Examiner or Purdue rely on the '331 filing date in response to a prior art rejection. In addition,

all of the pertinent facts regarding the '331 patent were before the Examiner: the application, its disclosure, its inventors, and its dates. And the Examiner was aware that the '912 application "adds and claims additional disclosure not presented in the prior application." ('912 file history, Paper #9, June 12, 1995, p. 2). Except as expressly admitted, Purdue denies the averments of Paragraph 96.

97. Paragraph 97 accurately quotes the cited portions of the specification of the '912 patent except that the parenthetical phrase in the fourth block quote should read "(such as MS Contin®)" instead of "(such as MS Contin™)". Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 97.

98. Denied.

99. Admitted.

100. Paragraph 100 accurately quotes the cited portion of the prosecution history of the '912 patent except that it incorrectly inserts the word "as" between "hydromorphone formulations" and "set forth" in the second quotation. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 100.

101. Paragraph 101 accurately quotes the cited portions of the specification and prosecution history of the '912 patent except that the first word in line 3 of the second block quotation should be "to" instead of "with." Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 101.

102. Paragraph 102 inaccurately and incompletely quotes the cited portion of the prosecution history of the '912 patent. In its February 12, 1995 Amendment to this application, Purdue's attorney stated: "The in vitro dissolution data, such as that found in the '341 patent, *is*

but one of many factors which must be considered when formulating a particular drug composition. Such data are often not indicative of in-vivo effect, particularly in the case of opioids." The italicized portion was omitted from KV's quotation. The other portion of the Amendment quoted in Paragraph 102 is quoted accurately. Except as expressly admitted, Purdue denies the averments of Paragraph 102.

103. Paragraph 103 accurately quotes the cited portion of the specification and prosecution history of the '912 patent. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 103.

104. The Examiner withdrew the Section 102(b) rejection in the Office Action dated June 12, 1995. Except as expressly admitted, Purdue denies the averments of Paragraph 104.

105. Admitted.

106. Admitted.

107. The quotation in Paragraph 107 is correct but incomplete. In its August 8, 2000 brief, Purdue goes on to state: "But the central fact, ignored by Roxane, is that never at any time did the Examiner or Purdue rely on the filing date of the '331 patent in response to a prior art rejection for these claims." (Brief of Plaintiffs-Appellees, *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, No. 00-1398, (Fed. Cir. Aug. 8. 2000), p. 55). Except as expressly admitted, Purdue denies the averments of Paragraph 107.

108. Denied.

109. Denied.

110. The '042 patent is a divisional of the '912 application and as such has a substantially identical specification. The '042 specification contains the same statements set

forth in Paragraph 97. Except as expressly admitted, Purdue denies the averments of Paragraph 110.

111. Paragraph 111 accurately quotes the cited portions of the '042 file history. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 111.

112. The '295 patent is a continuation of the '912 application and as such has a substantially identical specification. The '295 specification contains the same statements set forth in Paragraph 97. Except as expressly admitted, Purdue denies the averments of Paragraph 112.

113. Denied.

114. An applicant's duty to disclose information material to patentability to the Examiner is defined by the version of 37 C.F.R. § 1.56, as amended, at the time a particular statement is made to the PTO. Purdue denies KV's characterization of 37 C.F.R. § 1.56. Except as expressly admitted, Purdue denies the averments of Paragraph 114.

115. Denied.

116. Denied.

117. Dr. Kaiko was not a named inventor of the '331 patent, which was assigned to Euroceltique. In his declaration submitted to the PTO, Dr. Kaiko identified himself as Vice President for Clinical Research for The Purdue Frederick Company, Norwalk, Connecticut. The PTO was informed of the relationship among Dr. Kaiko and the '331 inventors and the relationship between Dr. Kaiko and Euroceltique in PCT Application No. PCT/US92/10146, filed in the PTO on November 25, 1992. The prosecution history for the '331 patent does not indicate that the applicants for the '331 patent or their attorneys told the PTO that Purdue was

seeking FDA approval for the sale of OxyContin®. A reasonable examiner would assume that patent applicants and their assignee are interested in obtaining patent protection for the subject matter of the application. Except as expressly admitted, Purdue denies the averments of Paragraph 117.

118. Denied.

119. The applicants for the '331 patent knew that Dr. Kaiko was their co-worker and an employee of The Purdue Frederick Company, as did Purdue's attorney. Except as expressly admitted, Purdue denies the averments of Paragraph 119.

120. The PTO did know that Dr. Kaiko was affiliated with the named inventors of the '331 patent application. Except as expressly admitted, Purdue denies the averments of Paragraph 120.

121. Paragraph 121 accurately quotes the cited portions of U.S. Patent No. 3,965,256, which names Stewart Thomas Leslie as the sole inventor, except that: (1) the word "periods" in line 4 of the second block quotation should be "period"; (2) the word "were" in line 3 of the third block quotation should be "are"; and (3) the word "characteristics" should be inserted after "dissolution availability" in line 3 of the fourth block quotation. The prosecution histories of the '331, '912, '042, and '295 patents do not indicate that the Leslie '256 patent was cited by name or number during those prosecutions. The Leslie '256 patent is cumulative to and less pertinent than art that was cited. The '256 patent discloses certain "[s]low release pharmaceutical compositions comprising a combination of a higher aliphatic alcohol and a hydrated hydroxy-alkyl cellulose" in defined ratios to provide release "during a predetermined period of time of from 5 to 10 hours" for active ingredients not including opioid analgesics. ('256 patent, abstract; *Id.* 13:62 – 14:5). Except as expressly admitted, Purdue denies the averments of Paragraph 121.

122. Paragraph 122 accurately quotes the cited portions of the prosecution history of the Oshlack '598 patent except that: the words "up and" in line 2 of the first quotation should be "and up," and the word "and" should be inserted after "5 to 12 hours," in line 3 of the second quotation. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 122.

123. A controlled-release system known as the Contin® system was developed in the 1970s in the United Kingdom by Napp Laboratories Limited, a Purdue-associated company. The CANCER, 1989; 63:2275-83 article states that "the Contin release system . . . has been used successfully with a wide range of drugs." The article further states that "[t]he rate of release of active drug within the gastrointestinal tract [has] the result that the drug is delivered to the body at a specific, planned rate." The article co-authored by Dr. Kaiko (THE HOSPICE JOURNAL, 1990; 6(4):17-29) reports a Tmax of 2.38 +/- 0.17 hours for fasted subjects and 2.5 +/- 0.24 hours for fed subjects. Except as expressly admitted, Purdue denies the averments of Paragraph 123.

124. The article authored by Stuart T. Leslie (BRITISH JOURNAL OF CLINICAL PRACTICE 1981, 10:5-8) states that by varying the amounts and ratios of the components of the Contin® system, "it is possible to vary the rate of drug diffusion through the matrix and subsequent rate of dissolution" and that "[t]herefore diffusion and dissolution over a period of one hour to 12 hours *in vivo* can be realised." The text describing Figure 6 of the article states that the figure "illustrates the objectives of all personnel involved in the formulation of controlled release preparations, and shows the characteristic drug plasma concentration resulting from administration of a drug in conventional and controlled release drug forms." The text further states that "with the controlled release curve [of Figure 6] therapeutic activity can be seen

to exist over a period of some 12 hours in comparison to only three hours for the conventional dosage form." Except as expressly admitted, Purdue denies the averments of Paragraph 124.

125. The article co-authored by Dr. Kaiko (CLINICAL PHARMACOKINETICS 1986, 11:505-10) reports peak plasma levels for controlled-release morphine in the range of 2-4.5 hours. The paper cites other publications for the proposition that controlled-release morphine is dosed every 8 hours in some patients. The HOSPITAL THERAPY June 1986 comment was authored by Dr. Goldenheim. The Purdue Frederick Company received final FDA approval for MS Contin® on May 29, 1987. Except as expressly admitted, Purdue denies the averments of Paragraph 125.

126. Denied.

127. Denied.

128. The Leslie '256 patent was known to Mr. Oshlack and the attorneys prosecuting the '331, '912, '042, and '295 patent applications during the prosecution of the '256 patent. The unpublished work described in Paper #6 from the Oshlack '598 file history was known to Mr. Oshlack and the attorneys prosecuting the '331, '912, '042, and '295 patent applications during the prosecution of the Oshlack '598 patent. The Leslie '256 patent and the unpublished work described in the Oshlack '598 file history were less pertinent and cumulative to other facts that were before the PTO. The Contin® release system information was known to Dr. Kaiko. Except as expressly admitted, Purdue denies the averments of Paragraph 128.

129. Denied.

130. Denied.

131. Denied.

132. The information in Paper #6 from the Oshlack '598 file history was known to Mr. Oshlack and Mr. Steinberg during the prosecution of the Oshlack '598 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 132.

133. Denied.

134. Purdue's MS Contin® controlled-release morphine tablets were made using the Contin® matrix, which included a hydroxy-alkyl cellulose and a higher aliphatic alcohol. Examples 6-11 of the '331 patent and Examples 7-12 of the '912, '042, and '295 patents disclose formulations that include a hydroxyethylcellulose and cetostearyl alcohol. MS Contin® tablets meet the dissolution limitations of certain claims of the '331 and '912 patents. The article co-authored by Dr. Kaiko (CLINICAL PHARMACOKINETICS 1986, 11:505-10) reports peak plasma levels for controlled-release morphine in the range of 2-4 hours. The paper cites other publications for the proposition that controlled-release morphine is dosed every 8 hours in some patients. Except as expressly admitted, Purdue denies the averments of Paragraph 134.

135. At least in 1986, at the time he co-authored the article referred to in Paragraph 134, Dr. Kaiko had information about certain controlled-release morphine tablets. The commercial sale of controlled-release morphine was expressly placed before the PTO in the prosecution of the '912, '042 and '295 patents in suit and was disclosed in the Oshlack '598 patent cited during the prosecution of the '331 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 135.

136. Denied.

137. The prosecution histories of the '331, '912, '042, and '295 patents do not indicate that Purdue and its attorneys cited information about controlled-release codeine formulations to the PTO during the prosecution of those patents. That information was less pertinent than and

cumulative to other facts that were before the PTO. Purdue's controlled-release codeine product was made using the Contin® controlled-release system, which included a hydroxy-alkyl cellulose and a higher aliphatic alcohol. Examples 6-11 of the '331 patent and Examples 7-12 of the '912, '042, and '295 patents disclose formulations that include a hydroxyethylcellulose and cetostearyl alcohol. The authors of the Beaver et al. article (J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 1978; 207:92-100) "hypothesize that the high oral/parenteral relative potency ratios of codeine and oxycodone relative to morphine and its congeners are . . . [due to] methylation at position 3 in codeine and oxycodone [that] protects these drugs from rapid first-pass metabolism." The article also states that oxycodone "bears a structural relationship to codeine analogous to the relationship of oxymorphone to morphine." The abstract co-authored by Dr. Kaiko (ASCO PROCEEDINGS March 1986; 5:255) reports peak plasma levels for controlled-release codeine (CRC) in the range of 2-4 hours. The abstract states that the data "indicate comparable overall bioavailability between CRC and immediate-release codeine forms with CRC providing delayed and attenuated peak plasma concentration. The results are generally similar to those obtained in comparisons of controlled- and immediate-release morphine." The J. PAIN & SYMPTOM MANAGEMENT 1994; 9:363-71 article was co-authored by employees of Purdue Frederick Canada and reports on a study in which patients received 100, 200, or 300 mg of controlled-release codeine every 12 hours. The J. PAIN & SYMPTOM MANAGEMENT 1995; 10:612-23 article was co-authored by employees of Purdue Frederick Canada. Purdue's controlled-release codeine product provides pain relief for patients with mild to moderate pain. Except as expressly admitted, Purdue denies the averments of Paragraph 137.

138. At least in 1986, at the time he co-authored the abstract referred to in Paragraph 137, Dr. Kaiko had information about certain controlled-release codeine tablets. Except as expressly admitted, Purdue denies the averments of Paragraph 138.

139. Denied.

140. The prosecution histories of the '331, '912, '042, and '295 patents do not indicate that Purdue and its attorneys cited the '836 and '985 patents to the PTO during the prosecution of the '331, '912, '042, and '295 patents. The '836 and '985 patents are prior art to Purdue's '331, '912, '042, and '295 patents. The '836 and '985 patents were issued on the dates alleged, describe work done at Napp Laboratories Limited, a Purdue-associated company, and were assigned to Euroceltique. The '836 and '985 patents are cumulative to and less pertinent than art that was cited. Paragraph 140 accurately quotes the cited portion of the specification of the '836 and '985 patents. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 140.

141. The prosecution histories of the '331, '912, '042, and '295 patents do not indicate that Purdue and its attorneys cited the '984 patent to the PTO during the prosecution of the '331, '912, '042, and '295 patents. The '984 patent is prior art to Purdue's '331, '912, '042, and '295 patents. The '984 patent was filed and issued on the dates alleged, describes work done at Napp Laboratories Limited, and was assigned to Euroceltique. The '984 patent is cumulative to and less pertinent than art that was cited. Paragraph 141 accurately quotes the cited portion of the specification of the '984 patent except that the word "level" in the second-to-last line of the quotation should be "levels." Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 141.

142. The prosecution histories of the ‘331, ‘912, ‘042, and ‘295 patents do not indicate that Purdue and its attorneys cited information regarding controlled-release dihydrocodeine tablets disclosed in the ‘984 patent to the PTO during the prosecution of the ‘331, ‘912, ‘042, and ‘295 patents. Information on dihydrocodeine was cumulative to and less pertinent than the art that was already before the PTO. The ‘984 patent specification describes clinical studies on controlled-release dihydrocodeine. (‘984 patent, 6:34-7:58). The controlled-release dihydrocodeine tablets disclosed in Examples 1-6 of the ‘984 patent disclose formulations that include a hydroxyethylcellulose and cetostearyl alcohol, and provide peak plasma levels at between 2-4 hours. The ‘984 patent reports a peak plasma level of 130 ng/ml at 3 hours for the tablet described in Example 1, and a peak plasma level of 205 ng/ml at 1 hour for immediate release dihydrocodeine. The clinical study evaluating “the control of moderate to severe pain in osteoarthritis” described at 7:1-58 of the ‘984 patent reports similar pain assessment scores for patients taking controlled-release or immediate-release dihydrocodeine. The CURRENT MEDICAL RESEARCH AND OPINION 1992; 13:37-48 article cites study results “confirm[ing] that the controlled-release formulation [of dihydrocodeine] did have significantly later tmax and lower Cmax values than the normal-release product and that the bioavailability was similar for both formulations at the same total daily dose.” This article also cites study results “confirm[ing] that CR 60 mg dihydrocodeine tablets given twice daily were as efficacious as the normal-release tablet, given 4-times daily to the same total daily dose, in the treatment of moderate to severe pain” in osteoarthritis patients. Except as expressly admitted, Purdue denies the averments of Paragraph 142.

143. Denied.

144. At least at the time Mr. Steinberg prosecuted the application for the ‘984 patent, he had knowledge of the information contained therein. Except as expressly admitted, Purdue denies the averments of Paragraph 144.

145. Denied.

146. U.S. Patent No. 4,844,909 issued on July 4, 1989 and is assigned on its face to Euroceltique. The ‘909 patent is prior art to the ‘331, ‘912, ‘042, and ‘295 patents. The ‘909 and ‘984 patents each have the same named inventors and were both prosecuted by the same attorney. The ‘909 patent states that the tablets of Examples 1-3 were made using hydroxyethylcellulose and cetostearyl alcohol. Examples 6-11 of the ‘331 patent and Examples 7-12 of the ‘912, ‘042, and ‘295 patents disclose formulations that include a hydroxyethylcellulose and cetostearyl alcohol. The ‘341 patent is a continuation of the application that issued as the ‘909 patent and has the same specification as the ‘909 patent. Paragraph 146 accurately quotes the cited portions of the specification of the ‘909 patent and the prosecution history of the ‘341 patent except that “predicated” should be “predicted” in the second-to-last line of the second block quotation, and the first word of the third block quotation should not be capitalized. Purdue denies KV’s characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 146.

147. The ‘341 patent is a continuation of the ‘909 patent. Accordingly, the two patents have substantially identical specifications. Both the ‘909 and the ‘341 patents were cited by the inventors and their attorneys to the PTO in the specification of the ‘331 patent. Both the ‘341 and ‘909 patents are prior art under 35 U.S.C. § 102. Purdue filed a Terminal Disclaimer in the ‘331 application to obviate a possible rejection of the ‘331 claims for obviousness-type double

patenting over the claims of the ‘341 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 147.

148. The ‘909 patent states that the tablets of Examples 1-3 were made using hydroxyethylcellulose and cetostearyl alcohol. Examples 6-11 of the ‘331 patent and Examples 7-12 of the ‘912, ‘042, and ‘295 patents disclose formulations that include a hydroxyethylcellulose and cetostearyl alcohol. The tablets disclosed in ‘909 Examples 1-3 meet the dissolution limitations of claim 1 of the ‘331 patent. The tablets disclosed in ‘909 Example 1 meet the pH independence limitations of claim 1 of the ‘331 patent. The controlled-release tablets disclosed in ‘909 Example 1 provided a peak plasma level of 2-4 hours in the clinical study reported in the ‘909 patent. Paragraph 148 accurately quotes the cited reply to correspondence (J. OF CLINICAL ONCOLOGY, 1998:17:738). Purdue denies KV’s characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 148.

149. The ‘341 patent is a continuation of the ‘909 patent. Accordingly, the two patents have substantially identical specifications. Both the ‘909 and the ‘341 patents were cited by the inventors and their attorneys to the PTO in the specification of the ‘331 patent. Both the ‘341 and ‘909 patents are prior art under 35 U.S.C. § 102. Purdue filed a Terminal Disclaimer in the ‘331 application to obviate a possible rejection of the ‘331 claims for obviousness-type double patenting over the claims of the ‘341 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 149.

150. The ‘909 patent was known to the applicants for Purdue’s ‘331 patent and to Purdue’s attorneys, and was cited by them to the PTO in the ‘331 application. The ‘909 patent

was cumulative to and less pertinent than the art that was cited. Except as expressly admitted, Purdue denies the averments of Paragraph 150.

151. Denied.

152. The specification of the '331 patent contains the passage quoted in Paragraph 73 and referred to by Paragraph 152. Purdue denies KV's characterization of that passage. At least at the time Mr. Steinberg prosecuted the applications for the '836 and '985 patents, he had knowledge of the information contained therein. Mr. Oshlack, Dr. Kaiko, and one or more of the attorneys knew, at various times, of one or more of the controlled-release formulations of morphine, codeine, dihydrocodeine, and hydromorphone. Except as expressly admitted, Purdue denies the averments of Paragraph 152.

153. Denied.

154. Denied.

155. Denied.

156. Purdue repeats and incorporates its reply to Paragraphs 128, 143, and 152. Morphine, dihydrocodeine, hydromorphone, and oxycodone are all opioid analgesics. Paragraph 148 incompletely quotes a portion of the CLINICAL THERAPEUTICS 1996; 18(1): 95-105 article. The full quote is: "*In developing CR oxycodone, we* intended to produce a formulation that, *when administered according to the correct dosing guidelines,* mimicked the C_{max}, C_{min}, and percent fluctuation in plasma *oxycodone* concentrations of IR *oxycodone* at steady state." The italicized portion was omitted from the quotation in Paragraph 148 and refers to the controlled-release oxycodone formulation of the patented invention, not to any prior art formulation. As one of the authors of the cited article, Dr. Kaiko knew of the full quotation at the time the cited

article was prepared and published. Except as expressly admitted, Purdue denies the averments of Paragraph 156.

157. Purdue denies KV's speculation about the mental processes of the Patent Examiner and the averments of Paragraph 157.

158. Based on reasonable investigations, and in the absence of a specific identification of a citation by KV to a page or even a volume number within the OxyContin® NDA, Purdue is unable to confirm, and therefore denies, that the quoted statement appears in the NDA. Except as expressly admitted, Purdue denies the averments of Paragraph 158.

159. Denied.

160. Denied.

161. Example 17 of the '912, '042, and '295 patents provides support for the statements in Purdue's '912, '042, and '295 patents discussed in Paragraph 160. Except as expressly admitted, Purdue denies the averments of Paragraph 161.

162. Denied.

163. Paragraph 163 inaccurately quotes Dr. Kaiko's July 16, 1990 memorandum. The first block quotation should read:

> Theoretically, oxycodone has an ideal combination of *a* short elimination half-life and high oral to parenteral bioavailability for a controlled-release opioid analgesic. This combination of characteristics is not shared by any other morphine-like agonist analgesic. The shorter *the* elimination half-life, the sooner *steady-state and therefore stable pain control is achievable; the greater the oral to* parenteral bioavailability the less intra- and interindividual variation in bioavailability and, thus, the more efficient the titration process.

The italicized portion was omitted from KV's quotation. The other quotations in Paragraph 163 are accurate except that "in the face" should be "in face" in the second quoted sentence and there is no comma after "over morphine" in the fourth quoted sentence. Purdue denies KV's

characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 163.

164. Paragraph 164 accurately quotes the cited portion of Dr. Kaiko's September 28, 1993 memorandum except that "that" should be "than" in line 4 of the block quotation. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 164.

165. Paragraph 165 accurately quotes the cited portions of Dr. Kaiko's September 28, 1993 memorandum. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 165.

166. Paragraph 166 accurately quotes the cited portions of Dr. Kaiko's October 1993 memorandum except that: the "s" in "short half-life of elimination" should be capitalized; there should be a hyphen in "steady-state" whenever it appears; the memo refers to "less variation" (singular, not plural) in plasma oxycodone concentrations; and the last quotation in the table should begin "any such drug," not "any drug." Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 166.

167. Purdue has sponsored and supported numerous clinical studies, including the one cited by KV in Paragraph 167. Purdue denies KV's characterization of these studies. The "Kalso" study was conducted at Helsinki University Central Hospital in Finland beginning on February 22, 1994. The Kalso study was a single-center study examining the analgesic effectiveness of OxyContin® and MS Contin® and how the pharmacokinetic profile related to pain intensity in patients with cancer pain. Except as expressly admitted, Purdue denies the averments of Paragraph 167.

168. The Kalso study ("Protocol No. OC93-0303") was concluded on May 16, 1995. The study results were summarized in a final Study Report dated October 17, 1996. Purdue updated the FDA with the study results after the FDA had approved the OxyContin® NDA. Dr. Kaiko signed the Study Report on October 25, 1996. Except as expressly admitted, Purdue denies the averments of Paragraph 168.

169. Admitted.

170. Denied.

171. The Kalso study was completed on May 16, 1995. The '912 patent issued on August 27, 1996. The '042 patent issued on April 16, 1996. The '295 patent issued on August 12, 1997. Purdue did not disclose the Kalso study to the PTO, nor was there any reason that Purdue should have disclosed it. The study was less pertinent than and cumulative to other facts that were before the PTO. Dr. Kaiko was aware of the study as of August 16, 1996**.** Except as expressly admitted, Purdue denies the averments of Paragraph 171.

172. Purdue funded a clinical study, known as the "Berman" or "Mucci-Lo Russo" study, that was conducted between June 1, 1994 and December 27, 1995. The '912 patent issued on August 27, 1996. The '042 patent issued on April 16, 1996. The '295 patent was filed on March 19, 1996 and issued on August 12, 1997. Except as expressly admitted, Purdue denies the averments of Paragraph 172.

173. The results of the Berman study ("Protocol No. OC92-1001") were summarized in a final Study Report dated September 27, 1996. Purdue updated the FDA with the study results after the FDA had approved the OxyContin® NDA. The Study Report indicates that it was reviewed by Dr. Kaiko. As of September 27, 1996, Dr. Kaiko was aware of the pendency of the '295 patent application. On August 16, 1996, Dr. Kaiko provided comments on the study

results**.** Purdue did not disclose the Berman study to the PTO, nor was there any reason that Purdue should have disclosed it. The study was less pertinent than and cumulative to other facts that were before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 173.

174. Admitted.

175. Paragraph 175 states the correct citation to the article publishing the results of the Berman study but incompletely and inaccurately quotes page 243 of the article. The first phrase of the first quotation ("Dose titration to effect was similar with the two treatments") is found in the section entitled "Analgesia." The second phrase of that first quotation occurs in the next section, entitled "Acceptability of therapy and quality of life," which does not address dose titration. The full sentence reads: *"At the end of the study, 74% of patients in the CR oxycodone group and 77% in the CR morphine group rated therapy good to excellent, with* no statistically significant differences between treatments." The italicized portion, as well as over 15 additional lines of text and a section heading between the first and second phrases, was omitted from KV's first quotation. The second quotation in Paragraph 175, from page 248 of the article, is correct. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 175.

176. Paragraph 176 accurately quotes the cited portion of the article publishing the results of the Berman study. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 176.

177. Purdue employees have co-authored many articles, including the ones cited by KV in Paragraph 177. Purdue admits that the CANCER 1989; 63:2284-88 article was co-authored by Dr. Kaiko. Purdue admits that the CANCER 1997; 79:1428-37 article was co-

authored by an employee of Purdue Frederick Canada. That article reports a mean final dose of controlled-release oxycodone of 124 +/- 22 mg and a mean final dose of controlled-release hydromorphone of 30 +/- 6 mg. For the 31 patients "with chronic cancer pain and stable analgesic requirements" who completed the study, "[t]he dose of oral oxycodone required to provide optimal analgesia without intolerable side effects ranged from 20-550 mg per day." The authors stated that "[t]his wide variability among patients is consistent with the results of previous studies with controlled-release morphine and controlled-release hydromorphone." Purdue admits that the PAIN 1997; 73:37-45 article was based on a Purdue-sponsored study. In that study, "[t]he mean daily dose of CR oxycodone at the end of titration was 123 mg and that of morphine 180 mg" and that "the patient-controlled titration resulted in a total mean daily opioid dose of oxycodone 148 mg compared with morphine 193 mg indicating patient activity in changing the opioid doses from the assumed ratio of 2:3." The article also states that "[d]uring the stable phases, significantly more ($P<0.05$) daily doses of escape analgesics were required during treatment with oxycodone . . . compared with morphine." Purdue admits that the JOURNAL OF CLINICAL ONCOLOGY, Oct. 1998; 16(10): 3222-29 article was co-authored by Purdue Frederick Canada employees. That article reports on a study of 32 enrolled patients, of whom 23 completed the study. The study reports a "mean dose of controlled-release oxycodone [of] 46.5 ± 57 mg every 12 hours versus 72.6 ± 102 mg every 12 hours for controlled-release morphine." The authors also state that the study results "indicate that the two drugs provide an equivalent level of pain control at morphine equivalent doses up to 592.5 mg." The article states of a different study: "A parallel group study in 101 cancer patients that compared controlled-release oxycodone with controlled-release morphine demonstrated that controlled-release oxycodone and controlled-release morphine can be used with equal facility for

around-the-clock therapy in the treatment of cancer pain." Purdue admits that the JOURNAL OF CLINICAL ONCOLOGY, Oct. 1998; 16(10): 3230-37 article was co-authored by Dr. Kaiko. That study included 156 patients analyzed for efficacy out of the initial enrollment of 180. The mean dose was "114 mg (range, 20 to 400 mg) in the CR and 127 mg (range, 40 to 640 mg) in the IR oxycodone group." Purdue admits that the CANCER INVESTIGATION, 1998; 16(8): 562-71 article was based on a Purdue-sponsored study. 44 patients in that study completed the full 12 weeks. The article states that "patients could have received a wide dose range of prestudy opioid analgesics. One double-blind study enrolled patients previously treated with 6-9 tablets of fixed-combination opioid/nonopioid analgesics (low dose group). The other study included patients treated with a single-entity, strong opioid or a high dose (>9 tablets) of fixed-combination analgesics (high-dose group)." The "final (up to week 12)" value reported for 51 patients was 158.6 ± 20.5 mg. Purdue admits that the JOURNAL OF PAIN & SYMPTOM MGMT., Oct. 1999; 18(4): 271-79 article was co-authored by a Purdue Frederick Canada employee. The article states that "[a]mong cancer patients completing the titration period, the mean daily dose of oxycodone (±SE) was 104 ± 20 mg of CR oxycodone and 113 ± 24 mg of IR oxycodone; among noncancer patients, daily doses were 41 ± 4 mg and 39 ± 4 mg, for those receiving the CR and IR formulations, respectively." Purdue admits that the PHARMACOLOGY & TOXICOLOGY, 1990; 67:322-28 article reports on a study of 10 patients with metastasized cancer who suffered from severe pain. Purdue admits that the CLINICAL PHARMACOLOGY & THERAPEUTICS, 1990; 47:639-46 article reports on a study of 20 patients with metastasized cancer and severe pain. Except as expressly admitted, Purdue denies the averments of Paragraph 177.

178. To the extent that Dr. Kaiko was a co-author of the articles cited by KV, he was aware of what those articles reported at the time the respective articles were published. The prosecution histories of the '912, '042, and '295 patents do not indicate that Purdue and its attorneys cited the studies and articles in Paragraphs 162-77 to the PTO during the prosecution of the '912, '042, and '295 patents. Those studies and articles were less pertinent than and cumulative to other facts that were before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 178.

179. Denied.

180. Denied.

181. Denied.

182. Admitted.

183. Admitted.

184. Paragraph 184 states a conclusion of law to which no responsive pleading is necessary. Except as expressly admitted, Purdue denies the averments of Paragraph 184.

185. Admitted.

186. In the litigation between Purdue and Endo, Endo made various allegations of inequitable conduct against Purdue, including allegations relating to the use of the phrase "surprisingly discovered" in the specification of the '912, '042, and '295 patents. Except as expressly admitted, Purdue denies the averments of Paragraph 186.

187. On January 5, 2004, this Court issued an Opinion and Order that found the '912, '042, and '295 patents infringed by Endo's proposed product but unenforceable for inequitable conduct, and enjoined Purdue from enforcing the patents. *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 2004 WL 26523, at *27 (S.D.N.Y. Jan. 5, 2004), *aff'd in part, vacated in part*, 438 F.3d

1123 (Fed. Cir. 2006). The bases for this Court's finding of materiality are found on pages *21-*24 of the opinion. Except as expressly admitted, Purdue denies the averments of Paragraph 187.

188. Paragraph 188 accurately quotes the cited portions of Dr. Kaiko's testimony discussed in this Court's January 5, 2004 opinion in *Endo*. (*See Endo*, 2004 WL 26523, at *21-22). Except as expressly admitted, Purdue denies the averments of Paragraph 188.

189. Paragraph 189 accurately quotes the cited portions of this Court's January 5, 2004 opinion in *Endo* except that the second block quotation fails to indicate the omission of the words "this Court finds" after the first word of the quotation. Except as expressly admitted, Purdue denies the averments of Paragraph 189.

190. This Court inferred that the *Endo* plaintiffs acted with intent to deceive. (*See Endo*, 2004 WL 26523, at *24-26). Except as expressly admitted, Purdue denies the averments of Paragraph 190.

191. On February 1, 2006, the Federal Circuit withdrew its original panel opinion of June 7, 2005 in *Endo*, and vacated and remanded to this Court. Paragraph 191 accurately quotes the cited portions of the Federal Circuit's February 1, 2006 decision in *Endo*. Purdue denies KV's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 191.

192. Teva began selling its generic copy of OxyContin® in March 2004. Endo began selling its generic copy in June 2005. In 2006, both Endo and Teva settled their suits with Purdue. Endo withdrew its generic copy in December 2006. Except as expressly admitted, Purdue denies the averments of Paragraph 192.

193. The Federal Circuit's February 1, 2006 opinion in *Endo* found that the materiality of Purdue's omissions was "relatively low" but vacated and remanded to this Court for reconsideration of its intent finding and, if necessary, reweighing of materiality and intent. *Endo*, 438 F.3d at 1134-35. In addition to addressing these points, Endo's briefs after remand attempted to re-argue the issue of the level of materiality, which had already been decided by the Federal Circuit. Purdue and Endo subsequently settled their lawsuit. After the *Endo* settlement, this Court invited another round of briefing on the remand issue from Purdue, Impax, and Boehringer. Again, both Boehringer and Impax chose to re-argue materiality. Except as expressly admitted, Purdue denies the averments of Paragraph 193.

194. Admitted.

195. Denied.

196. Paragraph 196 states a conclusion of law to which no responsive pleading is necessary. Except as expressly admitted, Purdue denies the averments of Paragraph 196.

197. Denied.

198. Paragraph 198 states a conclusion of law to which no responsive pleading is necessary. Except as expressly admitted, Purdue denies the averments of Paragraph 198.

199. Denied.

200. On May 10, 2007, counterclaim defendant The Purdue Frederick Company, which is not a plaintiff in this lawsuit, settled a four-year investigation by the United States Attorney's Office in the Western District of Virginia by pleading guilty to a single count of misbranding a drug under the FDCA. On the same date and as part of the settlement, three current and former executives pleaded guilty to a strict liability misdemeanor offense of misbranding a drug. As part of the settlement, The Purdue Frederick Company and the three

current and former executives have agreed to pay a total of $634.5 million. Except as expressly admitted, Purdue denies the averments of Paragraph 200.

201. Denied.

202. Denied.

203. Denied.

204. Denied.

205. Denied.

206. Denied.

207. When a physician prescribes a pharmaceutical product such as OxyContin®, unless that physician orders otherwise, pharmacies may or must, depending on applicable law, fill the prescription with either the brand name pharmaceutical product or its generic equivalent, if applicable. Except as expressly admitted, Purdue denies the averments of Paragraph 207.

208. Denied.

209. Purdue denies that it has engaged in anticompetitive conduct or an overall scheme. Paragraph 209 otherwise states a conclusion of law to which no responsive pleading is necessary. Except as expressly admitted, Purdue denies the averments of Paragraph 209.

210. Purdue denies that it has engaged in improper or exclusionary conduct. Purdue lacks information sufficient to form a belief about the remaining averments of Paragraph 210, and therefore denies them.

211. Purdue lacks information sufficient to form a belief about the averments of Paragraph 211, and therefore denies them.

212. Denied.

213. Denied.

214. Denied.

215. Purdue denies that it has engaged in conduct that has damaged KV. Purdue lacks information sufficient to form a belief about the other averments of Paragraph 215, and therefore denies them.

216. Denied.

217. Denied.

218. Denied.

219. Denied.

220. Denied.

221. Denied.

222. Denied.

223. Denied.

224. Denied.

225. Denied.

226. Denied.

227. Denied.

REPLY TO COUNTERCLAIM COUNT I

228. Purdue repeats and incorporates its reply to Paragraphs 1-227.

229. Denied.

230. Admitted.

REPLY TO COUNTERCLAIM COUNT II

231. Purdue repeats and incorporates its reply to Paragraphs 1-227.

232. Denied.

233. Denied.

234. Denied.

235. Admitted.

REPLY TO COUNTERCLAIM COUNT III

236. Purdue repeats and incorporates its reply to Paragraphs 1-227.

237. Denied.

238. Denied.

239. Denied.

240. There is an actual controversy between KV and counterclaim defendants as to the enforceability of the '912, '042, and '295 patents. Except as expressly admitted, Purdue denies the averments of Paragraph 240.

REPLY TO COUNTERCLAIM COUNT IV

241. Purdue repeats and incorporates its reply to Paragraphs 1-227.

242. Denied.

243. Denied.

244. Denied.

245. Denied.

246. Denied.

247. Denied.

248. Denied.

249. Denied.

250. Denied.

251. Denied.

252. Denied.

253. Denied.

254. Denied.

255. Denied.

REPLY TO COUNTERCLAIM COUNT V

256. Purdue repeats and incorporates its reply to Paragraphs 1-227.

257. Denied.

258. Denied.

259. Denied.

260. Denied.

261. Denied.

262. Denied.

263. Denied.

264. Denied.

265. Denied.

266. Denied.

REPLY TO COUNTERCLAIM COUNT VI

267. Purdue repeats and incorporates its reply to Paragraphs 1-227.

268. Denied.

269. Denied.

270. Denied.

271. Denied.

272. Denied.

273. Denied.

274. Denied.

275. Denied.

276. Denied.

277. Denied.

278. Denied.

REPLY TO COUNTERCLAIM COUNT VI

279. Purdue repeats and incorporates its reply to Paragraphs 1-227.

280. Denied.

281. Denied.

282. Denied.

283. Denied.

284. Denied.

285. Denied.

286. Denied.

REPLY TO COUNTERCLAIM COUNT VII

287. Purdue repeats and incorporates its reply to Paragraphs 1-227.

288. Denied.

289. Denied.

290. Denied.

291. Denied.

292. Denied.

293. Denied.

294. Denied.

295. Denied.

296. Denied.

297. Denied.

REPLY TO COUNTERCLAIM COUNT VIII

298. Purdue repeats and incorporates its reply to Paragraphs 1-227.

299. Denied.

300. Denied.

301. Denied.

302. Denied.

303. Denied.

304. Denied.

305. Denied.

306. Denied.

307. Denied.

REPLY TO COUNTERCLAIM COUNT VII

308. Purdue repeats and incorporates its reply to Paragraphs 1-227.

309. Denied.

310. Denied.

311. Denied.

312. Denied.

REPLY TO ALLEGATION OF INTENTIONAL INTERFERENCE WITH VALID BUSINESS EXPECTANCY

313. Purdue repeats and incorporates its reply to Paragraphs 1-227.

314. Denied.

315. Denied.

316. Denied.

317. Denied.

318. Denied.

319. Denied.

320. Denied.

321. Denied.

DEFENSES

322. Purdue's '912, '042, and '295 patents are not invalid and are enforceable.

323. KV has infringed and will infringe under 35 U.S.C. § 271 the claims of the '912, 042, and '295 patents.

324. Purdue has not violated Section One of the Sherman Act (15 U.S.C. § 1).

325. Purdue has not violated Section Two of the Sherman Act (15 U.S.C. § 2).

326. Purdue has not violated any state antitrust law.

327. Purdue has not interfered with any valid business expectancy that KV alleges that it has.

WHEREFORE, Purdue prays for judgment:

A. Dismissing KV's Counterclaims;

B. Adjudging that the '912, '042, and '295 patents are valid and enforceable;

C. Adjudging that KV has infringed the '912, '042, and '295 patents and that such infringement has been willful and deliberate;

D. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of KV's ANDA No. 78-506 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) to be a date which is not earlier than the last date of expiration of the '912, '042, or '295 patents;

E. Preliminary and permanently enjoining, pursuant to 35 U.S.C.

§§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., defendant KV, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product that infringes the '912, '042, and '295 patents;

F. Awarding Purdue damages, together with prejudgment interest and costs, as provided by 35 U.S.C. §§ 271(e)(4)(C) and 284;

G. Trebling the damages awarded, as provided by 35 U.S.C. § 284;

H. Declaring this an exceptional case and awarding Purdue its attorney's fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

I. Awarding Purdue such other and further relief as this Court may deem just and proper.

ROPES & GRAY LLP

July 5, 2007

s/Richard A. Inz

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CERTIFICATE OF SERVICE

I hereby certify that on July 5, 2007, I caused to be electronically filed PURDUE'S REPLY TO THE COUNTERCLAIMS SET FORTH IN DEFENDANT KV PHARMACEUTICAL COMPANY'S ANSWER AND COUNTERCLAIMS with the Clerk of the Court via CM/ECF. Notice of this filing will be sent by e-mail to all parties by operation of the court's electronic filing system. Parties may access this filing through the court's CM/ECF System.

s/Richard A. Inz
Richard A. Inz